



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,137	02/15/2002	Browning Jeffrey	08201.0027-00000	2907

65779 7590 05/14/2008
BIOGEN IDEC / FINNEGAN HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
----------	--------------

1645

MAIL DATE	DELIVERY MODE
-----------	---------------

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/077,137	Applicant(s) JEFFREY ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 20, 25-27, 29, 32, 33, 35, 36, 38-40, 42, 43, 45-47, 49, 50 and 52-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32, 33, 35, 36 and 38 is/are allowed.
- 6) ☒ Claim(s) 19, 20, 26, 27, 29, 39, 40, 42, 43, 45, 46, 47, 49, 50, 52, 53, 54, 55, 56, 57, 59, 60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-31-07 has been entered.

The amendment filed 10-31-07 has been entered into the record. Claims 19, 20, 25, 26, 27, 29, 32, 33, 35, 36, 38, 39, 40, 42, 43, 45, 46, 47, 49, 50, 52, 53, 54, 55, 56, 57, 58, 59, 60 and 61 are pending and under examination. Claims 1-18, 21-24, 28, 30-31, 34, 37, 41, 44, 48 and 51 have been cancelled.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

Priority

Applicants again argue the assignment of priority and that if the instant application is enabled for amino acids 8-41 and 95% variants then Applicants are entitled to priority to at least Application 60/181,684 and 60/183,356, this point is conceded in view of Applicants arguments and evidence.

The rejection of claims 19, 20, 25-27, 29, 32-33, 35, 36, 38-40, 42, 43, 45-47, 49, 50 and 52-60 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising an isolated B cell activating factor receptor (BAFF-R) of SEQ ID NO: 1 or a fragment comprising residues 1-51 of SEQ ID NO: 1 that binds B cell activating factor (BAFF), wherein the BAFF-R is optionally fused to the Fc region of an immunoglobulin it does not reasonably provide enablement for sequence variants, naturally occurring variants, allelic variants,

Art Unit: 1645

mammalian homologues or percent variants thereof and fusions to an immunoglobulin per se is withdrawn in view of Applicants evidence and arguments.

The rejection of claims 19, 20, 26, 27, 29, 32, 33, 36, 38-40, 43, 45-47, 50 and 52-60 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gross et al (WO/00/40716, published 13 July 2000) is withdrawn in favor of the new grounds of rejection set forth below.

The rejection of claims 19, 20, 26, 27, 29, 32, 33, 36, 38-40, 43, 45-47, 50 and 52-60 under 35 U.S.C. 102(e) as anticipated by Shu et al (U.S. Patent No. 6,475,987, issued November 5, 2002, filed May 5, 2000 with benefit for the claimed subject matter of TALL-1 receptor homologues to the provisional document of May 1, 2000, 60/201,012).

This rejection is withdrawn in view of the enablement of the instant priority documents 60/181,684 and 60/183,836. It is noted for the record that the claims of Shu et al [claims 10-17] drawn to the TALL-1 homologue receptor do not have written description in the Shu priority document 60/132,892 filed May 6, 1999.

If applicants believe that their claimed invention distinguishes over claims 10-17 of Shu et al in any manner they are invited to comment on the record. It is noted for the record that at least 60/181,684, filed 2-11-00 to which the instantly claimed application claims priority has an actual reduction to practice of a specie within the genus claim. This priority date provides prima facie evidence of an earlier invention as compared to Shu et al.

It is specifically noted that since Applicants are claiming the same or overlapping subject matter as Shu et al and that the polypeptide of SEQ ID NO:11 of Shu et al [claims 10-17] is identical to BCMA of SEQ ID NO:1 herein, an issue under 102(f) and 102(g) might remain to be resolved by the appropriate authority.

New Rejection

Claims 19, 20, 26, 27, 29, 39, 40, 42, 43, 45, 46, 47, 49, 50, 52, 53, 54, 55, 56, 57, 59, 60 and 61 are rejected under 35 U.S.C. 102(e) as anticipated by Gross et al US 2006/0067933 with priority to provisional Application 60/115,068 filed January 1, 1999 for BCMA compositions of SEQ ID NO:6, fusions).

With respect to the disclosure of the earliest priority document Gross et al '068 describe the polypeptides of the present invention a TACI isoform having only one cysteine-rich pseudo-repeat, TACI per se and a related B cell protein BCMA were found to bind the TNF ligand zTNF4, also known as neutrokin alpha, BAFF, Blys, TALL-1 and THANK would be useful to regulate the activity of ztnf4 (neutrokin alpha) on the activation of B cells (paragraph bridging pages 1-2). The figure demonstrates BCMA alignment and the particular domains of the proteins of the invention as described by Gross et al. The specification of the provisional document teaches the fusions of such proteins to heterologous protein, including heavy chain constant regions of immunoglobulins and further teaches administration *in vivo* (see pages 4-5) and a fragment of the BCMA receptor protein. The specification teaches compositions comprising such at pages 63, 73 and 74. As such, the compositions of the prior art anticipate the instantly claimed compositions.

Status of Claims

Claims 19, 20, 26, 27, 29, 39, 40, 42, 43, 45, 46, 47, 49, 50, 52, 53, 54, 55, 56, 57, 59, 60 and 61 are rejected. Claims 32, 33, 35, 36, 38 and 58 are allowable over the art of record, but maybe subject to an issue of 102(f)and/or (g) with respect to claims 10-17 of Shu et al above.

Conclusion

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645